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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,345	10/31/2006	Jerome Besse	030363-00003	6617
4372	7590	12/23/2010		
ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER GREENE, IVAN A	
			ART UNIT 1619	PAPER NUMBER
			NOTIFICATION DATE 12/23/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/567,345	Applicant(s) BESSE, JEROME	
	Examiner IVAN GREENE	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Finality Withdrawn

The Finality of the last Office Action is WITHDRAWN in order to clarify the prior rejections of record. The instant Office Action is made Final.

Status of the claims

Claims 1-26 and 28-31 are currently pending. Claim 27 has been canceled by applicant. Claims 1-26 and 28-31 are presented for examination on the merits.

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13-16 and 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over TIMMINS (US 6,031,004) and BALKAN (US 2003/0139434) as evidenced by TYLER (W.S. TYLER CANADA, product and price catalog), MARTIN (US 6,110,497) and SHIMIZU (US 6,328,994).

Response to Arguments:

Applicant's arguments filed 10/01/2010 have been fully considered but they are not persuasive.

Applicant's argument that "although the active ingredient is sieved in Timmins, the steps of adding additional excipients to the sieved active ingredient, followed by mixing and compressing, will result in a mixture containing particles that are larger than 710 microns" (p. 19, lines 11-14), is not considered persuasive because no supporting evidence has been submitted. Furthermore the instant specification indicates that the size is determined as follows:

[0026] In addition, when two dispersible tablets according to the invention are immersed in 100 ml water R, and they are stirred until the total dispersion of the particles being contained in such tablets, the thus obtained particle dispersion is homogeneous and wholly goes through a sieve with a nominal mesh opening of 710 μm (European Pharmacopeia, 4th Edition, Section 4-4).

Applicant's attention is drawn to paragraph 26 of the instant specification because the specification recites that the tables are immersed in 100ml of water and stirred until they reach a total dispersion prior to being sieved through a sieve with a nominal mesh opening of 710 μm . The water-soluble particles of the tablet composition will dissolve and will pass through the

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sieve. Only non-water soluble particles or poorly-water soluble particles, granules, or aggregates will remain that will need mesh openings of 710 μ m in order to pass through.

Applicant's arguments do not suggest that the product of TIMMINS does not meet the above immersion/stirring/dissolution prior to sieving and no data have been presented showing that the product of TIMMINS does not meet the above immersion/stirring/dissolution prior to sieving. Accordingly, Applicant's argument that the composition of TIMMINS will result in a mixture containing particles that are larger than 710 microns is not considered of sufficient weight to overcome the obviousness rejection, particularly in view of the immersion/stirring/dissolution prior to sieving guidance provided in the instant specification.

Applicant's argument that the phrase "dispersible or orodispersible" in the presently claimed invention is not properly construed as a statement of intended use because it describes a structural feature of the presently-claimed invention, is acknowledged. In response the examiner argues that those structural features that are in the body of the claim that confer such a function (i.e. dispersible or orodispersible) have been fully addressed.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over TIMMINS (US 6,031,004) and BALKAN (US 2003/0139434) as evidenced by TYLER (W.S. TYLER CANADA, product and price catalog) as applied to claims 1-11, 13-16 and 18-28 above, and further in view of BONHOMME (US 6,372,790).

Response to Arguments:

Applicant's arguments filed 10/01/2010 have been fully considered but they are not persuasive.

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Applicant's arguments regarding TIMMINS have been addressed above, and no separate arguments over BONHOMEE have been presented.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over TIMMINS (US 6,031,004) and BALKAN (US 2003/0139434) as evidenced by TYLER (W.S. TYLER CANADA, product and price catalog) as applied to claims 1-11, 13-16 and 18-28 above, and further in view of OHNO (US 4,017,598); and further evidenced by BENNET ("Pharmaceutical Production: An engineering guide," 2003, Institution of Chemical Engineers, Chapter 6, pp. 111-153).

Response to Arguments:

Applicant's arguments filed 10/01/2010 have been fully considered but they are not persuasive.

Applicant's arguments regarding TIMMINS have been addressed above, and no separate arguments over OHNO or BENNET have been presented.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over TIMMINS (US 6,031,004) and BALKAN (US 2003/0139434) as evidenced by TYLER (W.S. TYLER CANADA, product and price catalog) as applied to claims 1-11, 13-16 and 18-28 above, and further in view of VENKATESH (US 6,475,510); and further evidenced by BENNET ("Pharmaceutical Production: An engineering guide," 2003, Institution of Chemical Engineers, Chapter 6, pp. 111-153).

Response to Arguments:

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Applicant's arguments filed 10/01/2010 have been fully considered but they are not persuasive.

Applicant's arguments regarding TIMMINS have been addressed above, and no separate arguments over VENKATESH or BENNET have been presented.

Conclusion

Claims 1-26 and 28-31 are pending and have been presented for examination on the merits. Claims 29, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph; and claims 1-26 and 28-31 are rejected under 35 U.S.C. 103(a). No claims allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647